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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,552	WALLUKAT, GERD	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 30-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-25 and 30-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

AMENDMENT ENTRY

Amendment of 12/5/07 has been entered. Claims 1-25 and 30-35 are pending and are subject to restriction as follows.

RESTRICTION GROUPS

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 32 and 35, drawn to methods of detecting disease associated autoantibodies.

Group II, claim(s) 16-19, 22-25, and 33 drawn to various peptide(s) for use as a medicinal active substance, wherein the peptides are claimed as such, or claimed as being "immobilized"/ "bound to a solid phase", or claimed in a kit, as well as to methods of their production.

Group III, claim(s) 20-25 and 33, drawn to various recognition molecule(s) directed against various peptide(s), wherein the recognition molecules are claimed as such, or claimed as being "immobilized"/ "bound to a solid phase", or claimed in a kit, as well as to methods of their production.

Group IV, claim(s) 22-25 and 33, drawn to compositions of a peptide(s) and its recognition molecule(s), as well as to methods of their production.

Group V, claim(s) 30-32 and 35, drawn to methods of treating autoimmune disease(s) with the use of a peptide(s) "bound to a solid phase" or provided on a "chromatography device".

Group VI, claim(s) 32 and 35, drawn to methods of treating autoimmune disease(s) with the use of a peptide(s) per se.

Group VII, claim(s) 32, drawn to methods of treating autoimmune disease(s) with the use of a recognition molecule directed against a peptide(s).

Group VIII, claim(s) 32, drawn to methods of treating autoimmune disease(s) with the use of a both a recognition molecule(s) and a peptide(s).

Group IX, claim(s) 34, drawn to methods of screening medication(s) with the use of peptides and/or recognition molecules.

EXPLANATION OF CLAIM PLACEMENT IN RESTRICTION GROUPS

Regarding claims 22-25, these have been listed as being in one or more of Groups II-IV because of the "and/or" recitations in these claims.

Regarding claim 32, this has been listed as being in each of Groups I and V-VIII because of this claim would fall into one of these Groups, depending upon which choice is made from the Markush group of (a)-(e).

Regarding claim 33, this has been listed as being in each of Groups II-IV because of this claim would fall into one of these Groups, depending upon which choice is made from the Markush group of (a)-(e) in the "production of a medication".

Regarding claim 35, this has been listed as being in each of Groups I and V-VI because of this claim would fall into one of these Groups, depending upon which choice is made from the Markush group of methods recited in lines 1-2. (It is also noted that it is improper for applicant to claim the methods recited in lines 1-2 as a Markush group, because these methods are not functional equivalents of one another. The claim is thus rejectable under 35 USC 112, 2nd para. for its recitation of an improper Markush group, and applicant will be required to recite nonequivalent methods in different claims.)

REASONS INVENTIONS LACK UNITY

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention requires that applicant claim a single technical feature that provides a contribution over the prior art. Instantly the ISA has found numerous references that point to a lack of novelty and/or lack of an inventive step. Furthermore, the USPTO presently notes additional prior art that would point to a lack of novelty

and/or lack of an inventive step for one or more of the above listed inventions; see WO 01/76662, or its equivalent, US 7,309,488 (US 7,309,488 is cited on PTO-892).

It is further noted that the IPEA only examined the invention as it related to Raynaud's syndrome, and, to that extent, only examined compositions related to certain of the peptides, and only examined the use thereof in detection methods. Thus inventions relating to all of the other diseases (see election of species required infra) and to all of the other compositions (e.g. "recognition members") and to all of the other methods (e.g. treating a patient with a peptide, with a recognition member, etc.) have not been considered by the IPEA.

Even if there were not any prior art references that would point to a lack of novelty and/or lack of an inventive step, it is to be noted that Unity of invention permits one to claim one method of making a product, the product made, and the first recited use of the product made. Instantly, the first recited method claims are not drawn to a method of making a product. The first recited method is drawn to methods of detecting disease associated autoantibodies; these methods, apparently, can use one of a Markush group of various peptides (e.g. in claim 12) but are not limited to the use of these peptides. The first recited product is one of a Markush group of various peptides, for use as a medicinal active substance (claim 16); these claimed peptides are thus not intended for use as a reagent in the diagnostic method of Group I. Even if it could be argued that these peptides would be so used, it is considered that the peptides that could be used in the method of Group I constitute a larger set of peptides than those recited in Group II; there is thus not a correspondence, in scope, between the reagents/ products used in the method of Group I and the products claimed in Group II.

The recognition molecule(s) of Group III are different in composition from the peptide(s) of Group II. As such, the recognition molecule(s) of Group III constitute the second recited product(s) and do not have unity with the product(s) of Group II. Furthermore, the recognition molecules of Group III are not used as reagents in the

diagnostic method of Group I, as such, the recognition molecules of Group III do not have unity with the diagnostic method of Group I.

The product/compositions of Group IV, having both a peptide(s) and its recognition molecule(s), differ in their properties from the compositions of Group II, drawn to compositions of only a peptide(s) and from the composition of Group III, drawn to only a recognition molecule(s). The compositions of Group IV, differ in their properties from the compositions of Groups II and II; because, once a peptide(s) and the recognition molecule(s) of Group IV become bound to each other, the composition would not be capable of further binding a peptide(s) or of binding recognition molecule(s). The product of Group IV would thus have a different use from that of either of Group II or III; in fact, the examiner sees the composition of Group IV as merely being a "used composition" that would be formed when a therapeutic treatment is conducted with the use the products of either of Group II or III.

The treatment method of Group V lacks unity of invention with the method of Group I, since it is the second recited method.

The treatment method of Group VI lacks unity of invention with the method of Group V, since the treatment of autoimmune disease(s) with the use of a peptide(s) "bound to a solid phase" or provided on a "chromatography device" would involve an ex vivo treatment, in order to remove autoantibodies from a treated patient; while the treatment of autoimmune disease(s) with the use of a peptide(s) per se would involve the administration of the peptides to a patient, in order to block autoantibodies in vivo.

The treatment method of Group VII lacks unity of invention with any of the other Groups, since it is recited after all of the methods of Groups I and V-VI. More particularly, with respect to the treatment methods of Groups V-VI, the method of Group VII represents a different contribution over the prior art, since methods of Groups V-VI use autoantigen peptides, while the method of Group VII uses recognition molecules

thereto (e.g. antibodies against the peptides). The autoantigen peptides and the recognition molecules would be expected to have different effects when administered in the treatment of a patient, and thus one would be motivated to use these under different conditions.

The method of Group VIII lacks unity of invention with any of the other Groups, since it is recited after all of the methods of Groups I and V-VII. More particularly, with respect to the treatment methods of Groups V-VII, it is to be noted that a treatment in which one administers compositions of a peptide(s) and its recognition molecule(s) (as in Group VIII) would be expected to have a different effect upon a patient from the case in which one administers compositions of a peptide(s) (as in each of Groups V-VI) or in which one recognition molecule(s) (as in Group VII). Thus one would be motivated to employ the inventions of Groups V-VIII under different conditions.

The screening method of Group IX lacks unity of invention with any of the other Groups, since "screening" is recited after all of the methods of Groups I and V-VIII. It would be recognized in the art that a "method for screening medications" would represent a different contribution over the art than a method of using a medication in a method of treatment. Because the claim fails to positively state how any of the compositions selected from the Markush group of (a)-(e) is actually used in any method "for screening medications", it is impossible to further explain how this method differs from one or more of the methods of Groups I and V-VIII.

ELECTION OF SPECIES

In the event that applicant elects any one of Groups I or V-VIII, the following election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I, in the detection of, and for Groups V-VIII, in the treatment of, one of the species of autoimmune diseases/conditions recited as dilatative cardiomyopathy, Chagas' cardiomyopathy, myocarditis, preeclampsia, malignant hypertension, essential hypertension, refractory hypertension, pulmonary hypertension, psoriasis, or Raynaud's syndrome.

It is noted that the ISA considered that claims drawn to these various diseases/conditions did not have Unity of Invention.

In the event that applicant elects any one of Groups I-IX, the following election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Groups I-II, IV-VI and VIII-IX a peptide or the use thereof, selected from one of the species of Peptides recited as EYGSFF, SFFCEL, ARRCYND, PKCCDF, AESDE, CYIQFF, EDGECY, VRTVEDGECYIQFFSNAAVTFGTAI, AFHYESQ, ENTNIT, FWAFGR, GRAFCDV, ITEEAGY, ERFCGI, GRIFCD or ITTCHDVL; and

For Groups III-IV and VII-IX a recognition member or the use thereof, wherein the recognition member is directed against one of peptides recited as EYGSFF, SFFCEL, ARRCYND, PKCCDF, AESDE, CYIQFF, EDGECY, RTVEDGECYIQFFSNAAVTFGTAI, AFHYESQ, ENTNIT, FWAFGR, GRAFCDV, ITEEAGY, ERFCGI, GRIFCD or ITTCHDVL.

It is noted that each of these peptides is a different peptide, by virtue of having its own unique sequence. Thus these different peptides do not provide a single contribution over the prior art. The searches for the different peptides, or for the recognition molecules thereto, would need to be conducted separately, and the USPTO does not examine more than one peptide sequence.

Thus, if applicant elects any one of Groups I or V-VIII, applicant is required to elect a single disease state/condition in conjunction with the use of a single peptide species. The Office has not required that applicant elect a single disease state

for any of Groups II-IV and IX. Groups II-IV involve compositions per se, and it is irrelevant what disease state one might use these compositions for, in methods of detection or treatment. Group IX recites no disease states/ conditions. In the event that any of the methods of Groups I and V-VIII are rejoined with one of Groups II-IV or IX, then applicant will be required to elect a single disease/state condition in conjunction with the previously elected species of peptide or recognition member directed thereto.

In the event that applicant elects any one of Groups III-IV or VII-IX, the following additional election of species is required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For the case in which the elected invention involves a composition containing a "recognition member" or a method using such a composition, applicant is required to elect not only the peptide against which the "recognition member" is directed but, additionally, one species of "recognition member" recited as "an antibody, a lectin, an antisense construct, and or a chelator" (as in claim 21). These are all different compositions, and it is to be noted that any "lectin" or "chelator" would be a composition that would have been previously known in the art, irrespective of whether the "lectin" or "chelator" was known as a "recognition member" for one of the peptides instantly disclosed. As such, no "lectin" or "chelator" can possibly represent any contribution over the prior art. The antibodies and the antisense constructs are different compositions which would represent different contributions over the prior art (the Office cannot even determine how the antisense construct can be a proper Markush group member of claim 21, since an "antisense construct" is a "recognition member" for a nucleic acid, rather than for a peptide).

ADVISORIES TO APPLICANT

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/21/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644